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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,902	07/03/2003	Hiroshi Takeyama	Q76104	8672

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	**PAPER NUMBER**
1614	
MAIL DATE	**DELIVERY MODE**
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,902	TAKEYAMA ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1-3 and 16-17 are examined.

Applicant has amended claims 1-3 and 16-17, canceled claims 4, 6 and 7 and provided arguments for the patentability of claims 1-3 and 16-17 in the response filed 21 November 2006.

Applicant's arguments, see response, filed 21 November 2006, have been fully considered and are persuasive to the extent that the rejections under 35 USC §102, have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made. Any rejection not specifically stated in this Office Action has been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 16-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, claim 1 recites "a dose of 1mg-50mg/tumor volume (cm^3)" which is vague and indefinite because the mg per tumor volume is unclear as to whether it is mg per 1 cubic centemeter or a generic tumor volume expressed in cubic centimeters but not defined in the claims as to how many. Additionally, it is unclear whether the dose is controlled by the last two lines of the claim regarding the necrotic requirement such that these last two lines do or do not confusingly correspond to any particular mg per cubic centimeter but rather are only functionally defined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation n under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6284786 to Casciari et al. in view of "The antitumor effect to stomach cancer by benzyl alcohol," Meeting of Japan Surgical Society on April 12-14, 2000, issued on March 10, 2000, PP-1457 (listed on PTO Form 1449, dated 27 October 2003, with a translation provided by Applicant), hereafter referred to as "Reference PP-1457." in light of *Stedman's Medical Dictionary*, 25th Edition (1990), p. 1026-1027 (cited for definition purposes).

Casciari et al. teach that vitamin C has anticancer properties in breast cancer for example (see col 3 lines 50-52). In addition to breast cancer, Casciari et al. teach that multiple types of cancers can be treated(see col 2 lines 50-55) wherein the reference teaches that "levels of ascorbic acid and lipoic acid can be set according to the type of cancer afflicting the patient" and further teaches a combination therapy for treating lymphoma, pancreatic cancer and colorectal cancer (see cols 78). That Casciari et al. teach such a variety of cancers, those examples are representative of cancer in general and would reasonably include other cancer types such as stomach cancer.

Reference PP-1457 teaches that benzyl alcohol induced cell death by apoptosis in stomach cancer cells (in the cell line STKM). In reference to the limitation in instant claim 2 of "external administrating," adding the benzyl alcohol to the cultured cells in their dish would include externally administering the composition; in other words, the reference does disclose application of the benzyl alcohol directly into the cells. The reference also indicated:

> **Since we found out that Benzyl alcohol had antitumor effect to a stomach cancer, we report said effect herein.**

which, absent factual evidence to the contrary would have been *in vivo* and since the gut space is "external" to the body, would have been anticipated as a method of external administration.

Stedman's defines necrosis as "pathological death of one or more cells...resulting from irreversible damage" (p. 1026). Thus, absent any factual evidence to the contrary, the cell death occurring in the treatment methods of the prior art would be considered necrosis, according to the common medical definition by Stedman's, therefore meeting the limitation of "necrosis".

In addition, the following case law is believed to be relevant to the instant claim rejections:

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is *prima facia* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been

individually taught in the prior art." Therefore, would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine vitamin C and benzyl alcohol, motivated by their having been taught by the prior art to be useful in treating cancerous tumors, consonant with the reasoning of the cited case law.

Response to Arguments - 35 USC § 103

Applicant's arguments filed 21 November 2006 have been fully considered but they are not persuasive. Applicant argues in part that the vitamin C can be used in a range of 0.1 to 10 times 1 part of BA by weight. Although this limitation may be supported in the Specification and Declaration, it is not present in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1 181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant further argues that the Declaration filed 14 April 2006 shows a synergistic relationship between BA and vitamin C for the treatment of a tumor. The Declaration is insufficient in its allegation of synergism. Particularly because the results of the treatment must be unexpected and without any comparisons, the increase in cell death as shown on page 4 of the Declaration, is without more, expected.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

6 June 2007
MG

Ardin H Marschel 6/10/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER